No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICUS CURIAE* CONGRESSMAN LAMAR SMITH IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE [1]

Amicus Curiae Congressman Lamar Smith served as Chairman of the Committee on the Judiciary of the U.S. House of Representatives during the pendency of the Leahy-Smith America Invents Act. He was the lead sponsor of the bill and managed its consideration in the House. *Amicus Curiae* has no personal or financial interest in the parties to this litigation or in the outcome of this specific case. His sole interest in this appeal is that 35 U.S.C. § 102(a)(1) be interpreted in a manner faithful to the legislative text.

SUMMARY OF THE ARGUMENT

An inventor's sale to a third party, *in which the subject matter defined by the claims of the inventor's patent must be kept confidential*, cannot invalidate patent claims under the America Invent Act's new 35 U.S.C. § 102(a)(1). The provisions of § 102 that were repealed under the Act had formerly provided that such a "loss of right to patent" might be triggered by such inventor-attributable "on sale" activities. With the repeal of all such "loss of right to patent" provisions, new § 102 now contains only a requirement for "novelty" over "prior art." However, under new § 102(a)(1), the requirement for "novelty" is fully satisfied unless the subject matter defined by a claim becomes "available to the public." In this appeal, confidentiality obligations prevented the required public

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[1] This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than *Amicus curiae* or his counsel of record made a monetary contribution to the preparation or submission of this brief. Each party has consented to the filing of this brief.

disclosure of the details of the invention from taking place. Thus, under the Act, the inventor's patent claims here are not invalid under § 102.

Congress altered the patent law dramatically with the American Invents Act, including in ways that impact this appeal. The changes were based on a set of recommendations from the National Research Council of the National Academies. At the urging of the NRC, Congress abandoned the first-to-invent principle, a bedrock of patent statutes for 175 years. Congress did so in large measure because that principle *had complicated the law on "prior art" and fostered the creation of numerous "loss of right to patent" provisions*. Moreover, such features of U.S. patent law placed the United States out of step with every other country in the world.

Congress based its new patent statute on the first-inventor-to-file principle in order to fashion a simplified and internationalized set of conditions for patentability in new §§ 102-103. This allowed Congress to enact a new § 102 limited to a requirement for novelty. It further allowed a dramatic clarifying and streamlining of the definition for prior art.

The changes to the law arising from the drafting of new § 102's "prior art" provision involved retiring the phrase "known or used" from repealed § 102(a)'s definition of prior art, notwithstanding that this phrase had been used to define "prior art" in every patent statute since 1790. It was replaced with an *alter ego* term, "available to the public."

This new terminology is used internationally to define prior art, in part by excluding confidential or otherwise secret subject matter from qualifying as prior art. It is also used judicially in the United

States to explain that subject matter could qualify under repealed § 102(a) as "known or used" only when *publicly disclosed*. Most significantly, the term "available to the public" in new § 102(a)(1) now functions as a terminal qualifier limiting prior art arising from "in public use" or "on sale" activities to what renders the subject matter defined by the patent claims available to the public.

Thus, to the end of a simpler and more internationalized patent system, the new statute both eliminated "loss of right to patent" provisions in which inventor-attributable activities might bar a patent under old § 102 *irrespective of whether the subject matter defined by the claims was made publicly available* and similarly limited the "novelty" bar to patenting such that the subject matter defined by a claim must now be available to the public. The simplicity of the new statute makes it difficult to read in any other way.

Even if it could be so read, there would be no justification as a matter of patent policy to do so. Congress determined that preserving patentability so long as the subject matter of a patent claim had not been publicly disclosed would provide a continuing incentive to disclose novel and non-obvious subject matter. In contrast, the repealed law operated to encourage continued secrecy once the right to patent had been forfeited though "on sale" activities attributable to the inventor, even if secret. The America Invents Act aligns with the patent system's constitutional purpose to encourage disclosure and, thus, promote progress in useful arts by replacing that incentive for secrecy with a continuing incentive to disclose.

ARGUMENT

I. Congress Repealed 35 U.S.C. § 102 And Replaced It With A First-Inventor To File Statute Eliminating Each Of § 102's Bars To Patenting Except For Lack Of Novelty Over Prior Art.

A. The America Invents Act Made Historic Reforms To U.S. Patent Law By Adopting The First-Inventor-To-File Principle.

The America Invents Act was the product of a six-year congressional effort[2] to simplify and internationalize U.S. patent law.[3] The magnitude and importance of the changes made to the U.S. patent system through the Act were virtually without precedent in the more than 200-year history of the U.S. patent law.[4]

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[2] Prior to the introduction of the America Invents Act in 2011, Congress considered similar bills beginning in 2005, the most significant of which were the Patent Reform Act of 2005, H.R. 2795, 109th Cong.; Patent Reform Act of 2007, H.R. 1908, 110th Cong.; Patent Reform Act of 2008, S. 3600, 110th Cong.; and Patent Reform Act of 2010, S. 515, 111th Cong.

[3] Robert A. Armitage, *Leahy-Smith America Invents Act: Will It Be Nation's Most Significant Patent Act Since 1790?*, Washington Legal Foundation Legal Backgrounder Vol. 26, No. 21 (September 23, 2011), available at https://www.wlf.org/wp-content/uploads/2018/08/09-23-11Armitage_LegalBackgrounder.pdf.

[4] See generally, Robert A. Armitage. *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1 (2012), available at

The motivation for pursuing such an ambitious set of reforms to the patent law in a single bill arose from a set of sweeping recommendations from the National Research Council of the National Academies of Science. These recommendations were made in a 2004 report that was the product of the NRC's four-year study of the patent system.[5]

The NRC recommended eliminating a fundamental aspect of the U.S. patent law that had been in effect since at least the Patent Act of 1836.[6] It proposed to eliminate from U.S. patent law the ability for an inventor to rely on a *date of invention* to establish whether or not an invention was novel (and thus patentable) over "prior art."

The NRC urged that the United States return to a patent law principle found in the 1793 Patent Act.[7] Under the 1793 Patent Act, only the *filing date of a patent application* was relevant to assessing that an invention was not already "known or used," such that the invention could be considered "novel" and a valid patent could be secured on the inventor's application for patent.[8] The NRC recommended returning to this

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https://www.uspto.gov/sites/default/files/aia_implementation/armitage_pdf.pdf.

[5] National Research Council. 2004. *A Patent System for the 21st Century*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10976.

[6] Patent Act of 1836, 5 Stat. 117.

[7] Patent Act of 1793, 1 Stat. 318.

[8] In 1793, the Congress limited the availability of patents to subject matter "*not known or used before the application*" for patent.

principle such that the *date of invention* would have no continuing relevance in determining patentability.

A corollary to the adoption of this principle arises in the circumstance where different inventors assert that they each independently made the same discovery. In such a circumstance, because invention dates would be disregarded, the *first inventor to file* for a patent, even if not the *first inventor to make the invention*, would alone have the right to patent the invention.[9]

In effect, the NRC recommended that the United States abandon what is commonly referred to as the *first-to-invent* principle for determining patentability (and the inventor's right to a patent otherwise) and adopt instead a *first-inventor-to-file* principle. Doing so is one of the seminal changes to U.S. patent law Congress accomplished through the America Invents Act.[10]

Id., § 1.

[9] See NRC Report, *supra*, at p. 124, "The United States should conform its law to that of every other country and accept the first-inventor-to-file system."

[10] America Invents Act, § 3. See § 3(o), reporting the sense of Congress that "converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries."

B. Congress Internationalized Patentability Law, Including By Adopting The First-Inventor-To-File Principle, In Order To Simplify § 102 And Limit It To Novelty And Prior Art Provisions.

At the time the America Invents Act was enacted in 2011, the first-inventor-to-file principle was observed by *every country in the world* except the United States.[11] In addition, in every other country of the world, "prior art" was determined by a pair of straightforward considerations.

In the first-inventor-to-file patent systems outside the United States, prior art consists of essentially two elements: (1) subject matter *publicly disclosed* before the inventor's patent filing and (2) *disclosures made in earlier domestic patent filings*, but only if such earlier patent filings eventually become public (*i.e.*, either when such other applications for patent publish or issue as patents).[12] Congress enacted the first-inventor-to-file principle through the America Invents

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[11] See America Invents Act, § 3(p), reporting the sense of Congress that "converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries."

[12] In the 38 countries adhering to the European Patent Convention, "prior art" used for assessing novelty can arise from only two sources: (1) "everything made available to the public by means of a written or oral description, by use, or in any other

Act in part because of the opportunity it presented to incorporate into U.S. patent law some of the relative simplicity typically present in foreign patent systems.

To maximize the prospects for delivering on this objective, Congress needed to make a fresh start with the patent statute, repealing the statute's core provisions addressing patentability, 35 U.S.C. §§ 102-103. These sections had been respectively titled "*Conditions for patentability; novelty and loss of right to patent*" and "*Conditions for patentability; non-obvious subject matter.*" Congress enacted entirely new §§ 102-103 to replace them.

New § 102 now bears the truncated title "*Conditions for patentability; novelty.*" The comparison of this truncated title to the title of the repealed statute indicates that Congress had repealed, and not replaced, each of the "loss of right to patent" provisions that had formerly been part of § 102.

By jettisoning the "loss of right to patent" from new § 102, the remaining patentability law under new § 102 is now confined—as its truncated title indicates—solely to the question of *novelty* in light of the *prior art*. This title-to-title comparison alone dictates that the courts should reject any construction of the new statute that would carry over any "loss of right to patent" provision from the § 102 repealed to the new § 102.[13]

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way" and (2) "the content of European patent applications as filed." Convention on the Grant of European Patents (Oct. 5, 1973), Article 54.

[13] Congress enacted these new titles into law under the America Invents Act and they represent "positive law titles [that] constitute legal evidence of the law." 1 U.S.C. § 204.

The repealed § 102 from the 1952 Patent Act had contained seven separate subsections providing a collection of individual "prior art" and "loss of right to patent" provisions. With the repeal of the "loss of right to patent" provisions and the ability to simplify the law on "prior art" under the first-inventor-to-file principle, the America Invents Act was able to distill new § 102's conditions for patentability into a single subsection that set out all the subject matter that could now qualify as "prior art" and bar a patent for lack of novelty. This subsection is new § 102(a).

New § 102(a) is titled simply, "*Novelty; prior art,*" indicating that any subject matter that could qualify as "prior art" is now to be found in this single new subsection of the patent statute. Such § 102(a) "prior art" now represents the exclusive basis on which new § 102 imposes a "condition for patentability."

This reference to "prior art" in new § 102(a)'s title is significant for another reason. The appearance of the term "prior art" in § 102(a)'s title and elsewhere in new § 102 was the first time that the term "prior art" had appeared in § 102 itself. Prior to the America Invents Act, the only patentability-related section of the patent statute in which the term "prior art" had appeared was in § 103.[14]

The references to "prior art" in new § 102 were part of an effort by Congress to more clearly tie together new §§ 102 and 103 and to better align and

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[14] Under the 1952 Patent Act, it was merely implicit in the patent statute that the constituents of "prior art" in § 103 addressing non-obviousness were to be found in the prior-art relevant subsections of § 102, and not elsewhere in the statute. See *In re Bergstrom*, 427 F.2d 1394, 1401 (CCPA 1970), confining prior art for novelty purposes to § 102's patent-barring provisions.

more clearly link—and ultimately simplify—the "conditions for patentability" set out under these sections. Indeed, to fully understand and interpret new § 102's provisions, it is essential to understand the ties Congress constructed between these two new sections.

In this regard, repealed § 103 had provided an obviousness bar to patenting that applied "though the invention is not *identically disclosed or described* as set forth in section 102, if the differences between the subject matter sought to be patented and the *prior art* are such that the subject matter as a whole would have been obvious *at the time the invention was made.*"[15] The America Invents Act enacted a new § 103 that instead barred a patent for a *claimed invention* "notwithstanding that the *claimed invention* is not *identically disclosed* as set forth in section 102, if the differences between the *claimed invention* and the *prior art* are such that the *claimed invention* as a whole would have been obvious *before the effective filing date of the claimed invention.*"[16]

Comparing the italicized before-and-after text above, Congress made four significant changes that operate to clarify and unify the relationship between new § 102 and new § 103:

First, Congress made the word "disclosed" in new § 103 the generic term for indicating when an activity can result in the creation of "prior art" under new § 102(a)—or bear on obviousness under new § 103. While repealed § 103 used the alternative "disclosed or described" to reference when § 102 would operate to bar an invention for lack of novelty, under the

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[15] 35 U.S.C. § 103 [1952 Patent Act].

[16] 35 U.S.C. § 103 [America Invents Act].

America Invents Act, it is a *disclosure* that is necessary to create "prior art." Picking up on this simplified terminology, new § 102 now uses the words "disclosed" or "disclosure" no less than 18 times, while repealed § 102 did not make even a single use of either word.

Second, consistent with the first-inventor-to-file principle, new § 103 no longer permits the inventor to resort to a *date of invention* to assess non-obviousness. That assessment is now made with reference to the date of the inventor's patent filing. Because of the importance of patent filing dates, new § 103 utilizes the term "effective filing date," which is a term that the America Invents Act added as a new definition now found in new 35 U.S.C. § 100(i) . This same terminology is now used extensively in new § 102—in a total of six places.

Third, new § 103 adopts a second new definition, enacted as part of the America Invents Act, to provide greater precision in interpreting the new statute. This new definition appears in 35 U.S.C. § 100(j) and defines the term "claimed invention." As used in both new § 102 and § 103, a "claimed invention" refers to "the subject matter defined by a claim in a patent or an application for a patent." The term "claimed invention" now appears a total of 16 times in new § 102.

Fourth, although the term "prior art" from repealed § 103 appears again in new § 103, the context in which the term appears in the new law is different, *i.e.*, the term appears in the context of a first-inventor-to-file statute in which "prior art" is now referenced explicitly in new § 102(a). Given this new context, the same word from the repealed statute now has a quite different meaning, consistent with the first-inventor-

to-file statute in which the "loss of right to patent" provisions of the repealed law have not been reenacted.

As for the "prior art" provisions themselves, under new § 102(a) of the America Invents Act, the types of *disclosures* that now can bar patent claims are set out in two new paragraphs. First, § 102(a)(1), addresses *publicly disclosed* subject matter as prior art. Second, § 102(a)(2), establishes when disclosures from *U.S. patent filings of other inventors* can constitute prior art.

Parsing new § 102(a)(1), this paragraph operates to novelty-bar a patent claim based on "prior art" from any of three categories: if "the *claimed invention* was [1] patented, [2] described in a printed publication, or [3] in public use, on sale, or otherwise available to the public *before the effective filing date of the claimed invention*."

The third of these three categories can be restated more fully by incorporating the definition from new § 100(j). As so restated, new § 102(a)(1) can impose a novelty bar to patenting when the *subject matter defined by the claim* has been in public use, on sale, or *otherwise available to the public*.

C. Congress Replaced "Known," A Word Used To Define Prior Art In Patent Acts Since 1790, With "Available To The Public" To Provide A More Apt and Internationalized "Prior Art" Standard.

The phrase "known or used," up until the America

Invents Act was enacted in 2011, had been used to define prior art in every U.S. patent statute since 1790.[17] In contrast, the phrase "available to the public," now found in § 102(a)(1), had never before appeared in the provisions of the U.S. patent statute setting out "conditions for patentability."

That said, the term "available to the public" had been judicially recognized at the Federal Circuit as a synonym for the term "known," as used in repealed § 102(a) in the phrase "known or used."[18] Further, "available to the public" is a recognized term of art used in patent laws outside the United States to characterize subject matter that can qualify as "prior

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[17] In 1790, Congress provided patents could be granted to inventors for inventions "*not before known or used.*" § 1, Patent Act of 1790, 1 Stat. 109. As noted above, in 1793, the Congress further limited the availability of patents to inventions "*not known or used before the application*" for patent. § 1, Patent Act of 1793, *supra*. In 1836, Congress permitted an inventor to patent only subject matter "*not known or used by others before his ... discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer.*" § 6, Patent Act of 1836, *supra*. In 1870, Congress limited enforceable patent rights to subject matter "*not known or used by others in this country, and not patented, or described in any printed publication in this or any foreign country, before his invention or discovery thereof, and not in public use or on sale [in this country] for more than two years prior to his application.*" §§ 24, 61, Patent Act of 1870, 16 Stat. 198.

[18] "Section 102(a) establishes that a person cannot patent what was already known to others. ... Accordingly, in order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

art."[19]

Outside the United States, the term "available to the public" has long been interpreted to preclude subject matter that remains confidential or otherwise secret from constituting prior art and being used to invalidate a patent. Based on its use outside the United States—as well as its meaning as interpreted by the courts in the United States—it is an alternative (and fully descriptive) way of requiring that subject matter must be *publicly disclosed* to constitute prior art.

By 2011, Congress determined that the time had come to reformulate the statutory text to address the ongoing inaptness—or at least incompleteness—of this phrase "known or used" in setting out the actual limitation on subject matter qualifying as prior art.[20] At the same time, in rewriting § 102 in 2011, Congress was faced with the challenge of reducing the redundancy in two of § 102's subsections (repealed §§ 102(a) and 102(b)) that separately provided that subject matter "patented" or "described in a printed publication" could constitute prior art.

These partially overlapping subsections used different terminology to reference the categories of subject matter other than that arising from patents and printed publications that could constitute prior art.

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[19] European Patent Convention, *supra*, Article 54.

[20] By the time of the 1952 Patent Act, the continued use of the phrase "known or used" was being questioned by Congress given its generality. See H.R. REP. NO. 82-1923 (Appendix, Revision Notes) at p. 17, *i.e.*, "The interpretation by the courts of paragraph (a) [of old § 102] as being more restricted than the actual language would suggest (for example, 'known' has been held to mean 'publicly known') is recognized but no change in the language is made at this time."

Repealed § 102(a) used the phrase "known or used by others in this country," while repealed § 102(b) characterized such subject matter as being "in public use or on sale in this country."

Congress, in crafting new § 102(a)(1), took the approach of effectively concatenating these two subsections and replacing "known" with the more apt and more internationalized term "available to the public"—positioning the latter phrase as a terminal qualifier to limit the preceding categories of § 102(a)(1) prior art to subject matter *publicly disclosed*. Thus, this new qualifier—"or otherwise available to the public"—can be understood to define prior art under new § 102(a)(1) as being limited to the types of *publicly known* subject matter that could have qualified as prior art under repealed § 102(a).

As so limited, this new statute—like repealed § 102(a) before it—vindicates the constitutional function of the patent system to promote progress in useful arts. What is already "known" to the public needs no patent monopoly to encourage its disclosure, but the prospect of exclusive rights under a patent provides a continuing incentive to disclose what the inventor yet holds in confidence and yet remains secret, *i.e.*, has not yet been *publicly disclosed*.

Thus, it follows from the text of new § 102(a)(1) that both "public use" and "on sale" activities, whether or not such activities are attributable to the inventor, can novelty-bar a patent claim, but only *if the actual subject matter defined by the patent claim at issue did not remain confidential or otherwise secret, i.e.*, had become available to the public.

D. Congress's Adoption Of The First-Inventor-To-File Principle Permitted Elimination Of All § 102 "Loss Of Right To Patent" Provisions.

The decision to draft a new patent statute that was devoid of "loss of right to patent" provisions, long part of the patent law, was taken just as seriously by Congress as the companion decision taken in the America Invents Act to abandon a first-to-invent system that had been codified as part of the patent statute since 1836. It was a decision, however, that was made with a compelling justification.

In general, "loss of right to patent" provisions address *inventor-attributable* activities that can result in a particular inventor forfeiting the right to patent—even if the claims to the invention would otherwise have met the patentability requirements as new and non-obvious over the prior art. Such provisions were found in repealed 35 U.S.C. § 102(c), § 102(d), and § 102(f) and in the "in public use" and "on sale" provisions of repealed § 102(b).[21]

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[21] The repealed subsections of § 102 were those related to an inventor's abandonment" of the invention under repealed 35 U.S.C. § 102(c); premature foreign patenting by the inventor or its assignee under repealed 35 U.S.C. § 102(d); and a obviousness-type bar to patenting based on the inventor's private knowledge obtained from others (*OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997)) under repealed 35 U.S.C. § 102(f). As the courts had interpreted repealed § 102(b), it contained a further "loss of right to patent" provision under which an inventor forfeits the right to patent an invention based upon inventor-attributable activities placing an invention "in public use or on sale." This "loss of right to patent" bar was absolute since it can apply, irrespective of whether the subject

While such forfeitures might be justified policy-wise to preclude an excessive delay in the inventor seeking a patent once an invention had been fully commercialized, this policy justification has limited, if any, importance where the first-inventor-to-file principle applies.

In the first-inventor-to-file world, inventors have an imperative to promptly seek patents on inventions, once made, given the inability to use the date of invention to rescue patentability if the invention in question has been the subject of a pre-filing public disclosure. For this reason, Congress found little justification—whether for policy reasons or otherwise—for reenacting "loss of right to patent" provisions under the America Invents Act.

Moreover, maintaining such provisions, even if a cogent policy justification could have been articulated, would have detracted from congressional efforts to internationalize U.S. patent law by embracing the first-inventor-to-file principle. This would be particularly true of a forfeiture of the right to patent based upon inventor-attributable "on sale" or "public use" activities in which the subject matter defined by the patent claims was not made available to the public. *Maintaining a forfeiture of this type could have left the United States alone in the entire world with such a provision in its patent law.*

Also, given the focus on inventor-attributable activities, including activities of the inventor's assignee,

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matter defined by the patent claims had ever been made, much less been made available to the public. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998).

such "loss of right to patent" provisions invite discovery of the activities of inventors and their assignees to determine if the patent right has been forfeited. Such provisions in the patent law can greatly compromise the efficiency and effectiveness of yet another seminal change to the U.S. patent law, the new post-grant review procedures enacted as part of the America Invents Act. Congress provided the opportunity for any member of the public to challenge the validity of any newly issued U.S. patent on any ground that could be raised as a defense to the infringement of the patent, but in a proceeding designed with a one-year time limit for reaching a final decision—*a limit premised on Congress's determination that discovery burdens in the old law would be gone in the new.*[22]

Thus, not only did new § 102(a)(1) restrict any bar to patenting to activities producing a public disclosure of the subject matter defined by the claim of a patent—*through the overarching requirement for such subject matter to be made "publicly known" or "available to the public"*—but did so for compelling reasons, *i.e.*, in light of the overall context in which the America Invents Act was conceived and enacted.

E. Any Contention That New § 102(a)(1) Reenacted A "Loss Of Right To Patent" Provision Is Non-Textual.

It is beyond any dispute that the new patent statute under the America Invents Act included no "loss

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[22] America Invents Act, *supra*, § 6(d), adding Chapter 32 to title 35, United States Code providing for the "post-grant review" of patents that are subject to the first-inventor-to-file provisions of the America Invents Act.

of right to patent" provisions corresponding to repealed § 102(c), § 102(d), or § 102(f). However, Congress did reuse terminology found in repealed § 102(b) in new § 102(a)(1). Thus, the only possible textual basis for contending that any "loss of right to patent" provision might somehow remain in a new statutory provision—now titled only "Conditions for patentability; novelty"—lies in the use in new § 102(a)(1) of the carryover terms "in public use" and "on sale" as found in repealed § 102(b).

Under the old patent law, at least as interpreted by the courts, an inventor could suffer the "loss of right to patent" or forfeit the right to secure a patent claim under repealed § 102(b). Such a forfeiture could take place *irrespective of whether the subject matter defined by the claims was made available to the public* based upon "public use" or "on sale" activities that were (1) attributable to the inventor, (2) undertaken in the United States, and (3) took place more than one year before the inventor's U.S. patent filing.[23] This type of forfeiture bar did not apply where the activities in question could not be attributed to the inventor. In such a situation, the subject matter defined by the patent claims needed to be available to the public for a patent to be barred for lack of novelty over the prior art.[24]

The legislative history that accompanied the 1952 Patent Act explained that its § 102(b) was simply restating the law from the patent statute that had come

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[23] 35 U.S.C. § 102(b) [1952 Patent Act], as interpreted in *Pfaff*, *supra*.

[24] *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540 (Fed.Cir.1983).

before it—which the courts had long held to contain such a "loss of right to patent" bar.[25]

Assuming, however, that such a forfeiture-type provision based on inventor-attributable "public use" and "on sale" activities had *not* been part of the U.S. patent law before the America Invents Act was enacted, it is self-evident that the carryover language from repealed § 102(b) could not have itself created such a "loss of right to patent." As written, the "novelty" bar in new § 102(a)(1) cannot be read to mean that "public use" or "on sale" activities attributable to the inventor could result in the forfeiture of the inventor's right to patent—*irrespective of whether the subject matter defined by the claim was available to the public*. A plain reading of the text of the new statute reveals that it does not set out one rule for inventor-attributable "public use" or "on sale" activities and a potentially contradictory standard that would apply to such activities otherwise. Thus, any contention that a "loss of right to patent provision was reenacted in § 102(a)(1) is, at best, non-textual.

Any further contention that such a non-textual forfeiture provision nonetheless must somehow exist within the text of new § 102(a)(1) becomes no less frivolous given the legislative context in which § 102(a)(1) was enacted. Beyond question, the new patent law under the Act was intended to simplify and internationalize our patent law; it was designed to build more transparency into patentability determinations so

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[25] This legislative history provided that for both repealed § 102(a) and § 102(b) of the 1952 Patent Act, "[n]o change is made in these paragraphs [from the prior law] other than due to division into lettered paragraphs." H.R. REP. NO. 82-1923 (Appendix, Revision Notes), p. 17.

that, as in foreign patent systems, patent validity would not turn on secret information, not available to the public—accessible only through discovery and possibly only at the time a patent's validity might be litigated; and the Act expressly repealed the "loss of right to patent" provisions that had existed under the former law and did not reenact any of them. All this context reaffirms that the text of the new patent statute must mean what it plainly indicates—Congress had retired this "forfeiture" element of the patent law in enacting the American Invents Act—new § 102 is now devoid of "loss of right to patent" provisions.

Also, simply because the words "on sale" appear in both repealed § 102(b) and new § 102(a)(1) does not indicate that bars to patenting remain identical under those two provisions—and somehow provide the otherwise missing textual support. Given the quite different context in which the words "on sale" are used in the 1952 Patent Act and the America Invents Act, the contention that all the patent law associated with these words was unchanged is no more tenable than would be the contention that all the law associated with the words "prior art" is unchanged with the repeal of all the provisions in the patent statute setting out the conditions for patentability and their replacement with remarkably different ones.

Most importantly, however, *patent policy matters*. Congress acted, through the America Invents Act, to fulfill the constitutional imperative that the patent system must promote progress in useful arts. To promote progress, a patent law must encourage disclosure of inventions—including disclosures through the patenting process itself—so that such publicly dis-

closed inventions can serve as feedstock for other inventors to make further advances in technology.

Patent forfeiture provisions—including those relating to "on sale" activities in effect under the old patent law—have the effect of encouraging perpetual secrecy for an invention once the possibility for securing a patent has been lost. *Repealing such forfeiture laws can have the opposite effect.* The absence of a forfeiture bar encourages public disclosure through use of the patent system by providing an inventor a *continuing opportunity* to secure a patent on the subject matter that is both novel and non-obvious.

The simultaneous repeal of "loss of right to patent" provisions and the introduction of the first-inventor-to-file principle under the America Invents Act represented measures that work in tandem to effect constitutionally consistent patent policy. The first-inventor-to-file principle *encourages early disclosure* of inventions, once ready for patenting, through prompt patent filings. At that point, the absence of a forfeiture law preserves a *continuing incentive to disclose* novel and non-obvious subject matter through use of the patent system. Thus, neither patent policy nor the constitutional purpose of the patent system assist in the effort to contort the text of the new statute to find textual support for an inventor-forfeiture provision that is otherwise absent.

F. Congress Left No Tenable Ground On Which To Hold That More Than A Novelty Bar Remains in New § 102(a)(1).

What would this Court need to conclude to find that Congress had left the patent statute sufficiently unchanged that it now contains provision under which

inventor-attributable "on sale" activities could bar a patent irrespective of whether the subject matter defined by the patent claims had become available to the public?

Based on an analysis of the new statute above, the Court would need to make one of two untenable determinations in order to affirm the Federal Circuit's holding—

(1) the Court would need to find that Congress enacted in new § 102(a)(1) a "novelty" provision specific to inventor-attributable activities, but one that cannot be grounded on any possible reading of the actual text of a newly enacted statute—*given that § 102(a)(1) was enacted with an overarching requirement for public availability of subject matter that could constitute "prior art" and defeat "novelty."* or

(2) in the absence of finding any supportive statutory text, the Court would need to determine that the provisions of a repealed statute nonetheless carry over into a new statute simply because the same words "in public use" and "on sale" are found in both statutes—*even though doing so (1) would be entirely at odds with the context in which these words appear in the new statute; (2) refute good patent policy; (3) frustrate a historic legislative endeavor to simplify and internationalize our patent law; and (4) negate, rather than advance, congressional efforts to enact more transparent and less discovery-intensive patentability standards.*

In sum, there is no tenable ground on which this Court could take Congress's historic simplification and internationalization of the conditions for patentability in new § 102(a) and—as the Federal Circuit

did—claw the new law back to the old law that Congress had repealed.

II. Under The America Invents Act, "On Sale" Activities Must Make The Subject Matter Defined By A Claim Available To The Public In Order For § 102(a)(1) To Bar A Patent On The Claim.

This appeal deals specifically with "on sale" activities that are attributable to the inventor because they were undertaken by the inventor's assignee, the patent owner Helsinn. However, the new statute self-evidently treats all "on sale" activities the same, whether they are inventor-attributable activities or not. The statute cannot be applied as written if it is given one construction for "on sale" activities that are inventor-attributable and a potentially contradictory construction for activities that are not.

The new statute contains a terminal qualifier on subject matter that can qualify as prior art that cannot be simply disregarded. It states that: "the subject matter defined by a claim" (which is the new statutory definition for the term "claimed invention" in new § 100(j)) must be "on sale, or otherwise available to the public" for new § 102(a)(1) to bar a patent. As written, this language on its face precludes knowledge not available to the public from barring a patent.

As drafted in 1952, now-repealed § 102(b), which expressly provided that a patent could be barred based on "on sale" activities, served as a dual-purpose statute, at least as interpreted by the courts. As interpreted, it imposed both a "prior art" bar (applying

no matter to whom the "on sale" activities were attributable) and a "loss of right to patent" bar (specific to inventor-attributable activities).

The judicial interpretation of the 1952 statute as containing such a dual bar was not expressly precluded in the repealed statute given the open-ended, non-limiting language used in the text of the repealed law. In general terms, repealed § 102(b) simply required the "invention" (not the "claimed invention" defined as "the subject matter defined by a claim") to be "on sale" (but only if so in the United States) outside the one-year period. In addition, there was no overall qualifier on public availability, *i.e.*, the repealed statute did not specifically limit "on sale" activities where the subject matter defined by a claim was available to the public.[20]

Thus, as drafted and unlike the new § 102(a)(1), repealed § 102(b) could presumably accommodate both a "prior art" construction and an inventor-forfeiture function. And, of course, the 1952 legislative history explained that it did just that—since the 1952 Patent Act did not purport to be modifying the patent law with respect to the statutory conditions for patentability from the patent statute that had come before it.

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[20] Had Congress sought to reenact the former "loss of right to patent" bar based "on sale" activities, it most certainly would have reimposed the limitation to domestic activities—and could have readily done so by further qualifying new § 102(a)(1) so that a claimed invention that was in public use or on sale *in this country* as a result of activities attributable to the inventor or a joint inventor of the claimed invention would not be subject to the limitation on availability to the public. During the entire legislative process, no such qualification was ever considered.

According to the facts before the Federal Circuit, all that was *publicly disclosed* from the inventor-attributable "on sale" activities was that the patent owner had agreed "to supply ... 0.25 mg ... palonosetron products." However, the subject matter defined by the claims of the patent detailed a very specific formulation of that product to which the patent claims were limited (*i.e.*, "palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; from 0.005 mg/mL to 1.0 mg/mL EDTA; and from 10 mg/mL to about 80 mg/mL mannitol").

Had the "on sale" activities undertaken here *not* been attributable to the inventor, there could be no § 102 patent bar based upon such activities—either before or after the America Invents Act. The sole effect of the America Invents Act on this appeal must be, therefore, to apply this outcome in the case of non-inventor-attributable "on sale" activities equally to inventor-attributable "on sale" activities.

III. New § 102(b)(1)(B) Confirms The Sole Bar To Patenting Under § 102(a)(1) Arises From *Publicly Disclosed* Subject Matter.

In drafting new 35 U.S.C. § 102(b)(1)(B), Congress excluded as prior art *subject matter disclosed by someone other than the inventor*, otherwise constituting prior art under § 102(a)(1) to an inventor's patent, if the "subject matter disclosed had, before such disclosure, been *publicly disclosed* by the inventor."

For § 102(b)(1)(B) to operate properly, Congress needed to restrict this special exclusion from prior art to the circumstance where the disclosure by the inventor had triggered the start of the one-year "grace

period" set out in § 102(b)(1)(A).[27] This "grace period" is triggered only if the inventor has made a disclosure that would otherwise qualify as prior art under § 102(a)(1). The drafting challenge, therefore, was to *identify text to include in § 102(b)(1)(B) that would be co-extensive with § 102(a)(1)-type disclosures by the inventor.*

The term "disclosed," standing along, would not work for this purpose. This term is used in the new statute as a generic term that covers disclosures that could become prior art under both § 102(a)(1) and § 102(a)(2)—and, a patent-filing disclosure of the type described in § 102(a)(2) does not trigger the start of the "grace period."[28]

Congress solved this drafting challenge using the words *publicly disclosed*. Because Congress had limited § 102(a)(1) prior art to subject matter publicly disclosed, the use of the term *publicly disclosed* in § 102(b)(1)(B) removed the possibility that its prior art exclusion would apply, for example, to the situation where the inventor had made a non-public disclosure in a provisional patent application[29] that later

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[27] "A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under [§ 102](a)(1) if ... the disclosure was made by the inventor...." 35 U.S.C. § 102(b)(1)(A).

[28] The generic nature of the term "disclosed" in the new statute is most clear from new § 103 that now uses the phrase "disclosed as set forth in section 102" to reference subject matter disclosed under both § 102(a)(1) and § 102(a)(2).

[29] Under 35 U.S.C. § 111(b), provisional patent applications cannot issue as patents and never become public unless converted to a nonprovisional application or used as a basis for claiming priority under 35 U.S.C. § 119(e).

was abandoned and had never become public. Thus, *publicly disclosed* is the perfect synonym for *disclosed under § 102(a)(1)*.

If this *public* disclosure limitation had not been placed into the statute, an inventor could have filed and abandoned a provisional application *years before* someone else had independently discovered and published in the same subject matter. Without the word "publicly," the inventor could assert entitlement to exclude the later publication by someone else as prior art under § 102(b)(1)(B)—even if the prior art disclosure had appeared years after the inventor abandoned the provisional patent filing.

Congress avoided creating such a loophole in the new statute through the *publicly disclosed* limitation. By requiring the inventor to publicly disclose, thereby creating § 102(a)(1) prior art, and thereby triggering the start of the one-year "grace period," the inventor would be forced to seek a patent during the one-year period or forfeit the right to patent on the *publicly disclosed* subject matter altogether.

The text of § 102(b)(1)(B), thus, confirms that the patent statute now uses the term "publicly disclosed" interchangeably with the concept of "disclosed as set out in § 102(a)(1)." They can be regarded as perfect synonyms. Thus, to the extent the text of new § 102(a)(1) was not completely unambiguous that § 102(a)(1) was limited to *publicly disclosed* subject matter that could bar a patent, the choice of the term "publicly disclosed" in new § 102(b)(1)(B), as a synonym for what can bar a patent under § 102(a)(1), erases any possible ambiguity.

IV. The Mere Repetition Of The Words "On Sale" From The Repealed Statute Provides No Basis For Concluding The Law In The New Statute Remains Unchanged

The Federal Circuit opinion below appears to have considered the presence of the words "on sale" in the new statute as almost by itself a sufficient justification for referencing all the old "on sale" precedents and invoking all the old patent policy that had applied under the 1952 Patent Act. This is not a sufficient basis for overriding the new statutory context in which words from a repealed statute might be reused.

Like the words "on sale," the term "prior art" is reused in the America Invents Act from the 1952 Patent Act. The term "prior art" appears in repealed § 103 to reference a collection of activities that take place *before the inventor's date of invention*. Under the America Invents Act, a new § 103 uses this identical term in the new context of a first-inventor-to-file system. As part of that new context, the America Invents Act removed all references to the date of invention from the patent statute and did not reenact any of the provisions found in the 1952 Patent Act dealing with prior inventions of others being prior art.[30]

In this context, the reuse of the term "prior art" cannot sensibly be understood to mean that all the holdings in which the term was construed under the 1952 Patent Act have survived. The survival of meanings relating to the date of invention, for example, would be inconsistent with the first-inventor-to-file context of the use of the term in the new statute.

Finding that "on sale" carries with it every old

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[30] 35 U.S.C. § 102(g).

meaning, including the patent law that applied based upon the forfeiture or "loss of right to patent" arising from inventor-attributable activities that apply irrespective of whether the subject matter defined by a claim is available to the public, similarly makes no sense in the context of a new patent statute under which no reference to such "loss of right to patent" provisions is anywhere to be found. Like the term "prior art," the term "on sale" must be construed in its new statutory context—where there is no basis to conclude the repetition of these words somehow negated the explicit repeal of the "loss of right to patent" provisions.

V. Whatever Policy Justification May Have Existed For The "On Sale" Bar Applied By The Federal Circuit, It Has Disappeared Under The America Invents Act.

The policy rationale that must undergird the Federal Circuit decision is that at some point an inventor engaging in "on sale" activities must be forced to choose between seeking a patent and forfeiting the right to patent, even if such "on sale" activities are confidential and the invention remains secret. The courts have held that the prior patent laws had reflected such a policy by providing a one-year or two-year period from the start of "on sale" activities that were attributable to the inventor before such a forfeiture of the right to patent would be imposed.[31]

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[31] The patent statutes have historically contained either a one-year or two-year "grace period" during which "in public use" or "on sale" activities attributable to the inventor could be disre-

However, the manner in which such a bar has been implemented by the courts has always had elements that were more punitive than principled. For example, in *Pfaff v. Wells* the "on sale" bar was applied to an invention before it had ever been actually made—when it was merely "ready for patenting"—and applied when the commercialization activities were otherwise inconsequential, *i.e.*, one-off sales that were at most *de minimis*. The result of such an oversized bar has been to impose a burden on the inventor to seek a patent unjustifiably early, if for no other reason than the standard for "readiness" can be so subjective and threshold for triggering the bar can be so low.

For an invention never actually made in physical form nor yet available for purchase—or sold only in trifling quantities or "on sale" only for a matter of days beyond an arbitrary deadline—there is not now nor has there ever been any compelling patent policy that should demand absolute forfeiture of the right to patent. Whatever rule might be justified in the case of substantial, longstanding, and ongoing "on sale" activities (*i.e.*, sales in which profits from commercially significant quantities sold have been realized, with such sales taking place over a period of many years

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garded in determining patentability. By 1897, Congress had restated the primary conditions for patentability to permit an inventor to patent only subject matter "*not known or used by others in this country*, before his invention or discovery thereof, and not *patented or described in any printed publication in this or any foreign country*, before his invention or discovery thereof, or more than two years prior to his application, and not *in public use or on sale in this country for more than two years prior to his application*." Patent Act of 1897, 29 Stat. 692. In 1939, Congress reduced the two-year period to one year. § 1, Patent Act of 1939, 53 Stat. 1212.

before seeking a patent), it is hard to articulate a similar justification for barring a patent—as in this appeal—based upon a supply contract where nothing was ever supplied in domestic commerce before the patent was sought.

In any event, whatever rule might or might not have been justified policy-wise under the 1952 Patent Act requires rethinking under the America Invents Act's first-inventor-to-file principle that inherently encourages prompt patent filing in a manner that the old first-to-invent system did not. Most certainly, Congress would not have acted to expand such a forfeiture bar to encompass confidential "on sale" activities *taking place anywhere in the world*, in part given the fantastically negative implications of doing so as the America Invents Act was simultaneously creating post-grant review procedures required to meet a one-year deadline for adjudicating the potential patent invalidity implications of such activities.

The entire purpose of the patent system is to encourage disclosure over secrecy. Progress in the useful arts is promoted under the patent laws when inventors disclose their inventions so that others might improve upon them. *A patent act fulfilling this primary purpose of the patent laws would provide inventors with a continuing incentive to disclose rather than maintain secrecy.*

The first-inventor-to-file system operates to this end in part because prior art is measured based on the effective filing date of the claimed invention. Waiting a day too long to file for a patent means that new prior art, appearing even a day before the patent filing was accomplished, may render the invention no longer novel or obvious—and no longer patentable.

While a first-inventor-to-file system can be seen as encouraging a race to make an invention available to the public—through the patenting process—the "on sale" bar that the Federal Circuit imposed on this first-inventor-to-file system simply negates the incentive for public disclosure. Once the Federal Circuit's "on sale" bar takes hold for an invention not thereby made available to the public, the inventor has an incentive to continue the "on sale" activities without ever making the invention available to the public. *Continued secrecy becomes the only means for protecting the invention from copying once the right to patent has been forfeited.*

The *coup de grâce* to any notion of carrying the bar forward into the first-inventor-to-file world is its negation of any continuing incentive to disclose an invention as yet unavailable to the public—leaving the inventor with the sole option of continuing secrecy as the best means for securing economic benefit from continuing commercialization. In repealing—and not reenacting—a bar to a patent claim based upon "on sale" activities specifically attributable to the inventor *irrespective of whether the subject matter defined by the claim was available to the public*, Congress was being careful to reflect the policies that ought to govern a patent law calculated to promote progress in useful arts, by exalting a continuing incentive to disclose over encouraging continued secrecy.

CONCLUSION

The America Invents Act cannot—and should not for any sound policy reason—be understood to bar a patent for a claim based upon "on sale" activities attributable to the inventor in which the subject matter defined by the patent claim has not been made available to the public. That is how the statute was written and should be applied.

Respectfully submitted,

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